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TITLE: The Effect of Interactive Simulations on Exercise Adherence with Overweight and Obese Adults

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14. ABSTRACT This project was designed to evaluate the effect of videogame play on exercise motivation, self-efficacy, and adherence in overweight and obese adults. A prototype stationary exercise bicycle that integrated video game play capabilities was developed. Unique software was written and further modified to integrate the exercise equipment/video game components, and to capture and transfer data from the exercise bicycle ergometer to the study database computer. It allows performance data to be automatically transferred to the database during the exercise session, and eliminates the need for a separate television controller. In addition, the software requires minimal re-configuration for each participant, and provides simultaneous heart rate level monitoring displays for up to 8 cyclists. Following approval of a no-cost extension, a protocol was submitted to the local IRB in February 2009. The PI was unofficially notified of the first level approval in August 2009 with a requirement to identify a new medical monitor to replace the original that had been deployed. The study will proceed as soon as we are notified the second level review was successful and the start letter is received.					
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INTRODUCTION:

This study examines the effects of interactivity with video game play on exercise adherence, exercise motivation, and self-efficacy in overweight and obese Army personnel. Despite being younger, less obese, and more physically fit than the average American adult, many active duty personnel are challenged by overweight and obesity. These conditions adversely impact military readiness and mission-related success. While increased activity level has proven to be a critical element in weight loss and improved health, adherence to physical exercise programs has been problematic. Two important mediators of this relationship are self-efficacy and motivation to exercise. Interactive simulations such as video games are highly engaging and provide positive visual and auditory stimulation that may allow participants to enhance and maintain positive exercise behaviors. The project randomizes 60 active duty military participants into 2 exercise groups—one using video game-enhanced exercise bicycles and the other using non-enhanced exercise bicycles. A repeated measures experimental design is used to evaluate group differences in exercise adherence, self-efficacy, and exercise motivation. Secondary variables include cardiovascular fitness, exercise behavior indicators, physiologic changes, health perceptions, and quality of life. The longer-term goal of this effort is to improve the readiness of military personnel and the health status of the general public through the study of innovative applications of new and emerging technologies to treat behavioral health disorders.

BODY:

Task 1: Submit protocol for IRB and second level review approval

As planned the protocol was submitted to the local IRB in the first quarter of the new performance period. Unfortunately, the protocol was not reviewed until nearly six months after submission. The successful review required that a new medical monitor be identified prior to the local IRB forwarding the protocol for second level review since the originally named medical monitor had been deployed. A query in November indicated that the local IRB had not yet forwarded the protocol for second level review, no explanation was given for the more than three month delay.

Task 2: Evaluate, purchase, setup equipment and physiologic monitors

Substantial development on a prototype exercise bicycle for use in the study was completed during the first year of the award. As there was no commercially available stationary exercise bicycle with the capabilities required for the study, the project developed exercise equipment with an interactive video game unit. Unique software was written to integrate the components into a functioning unit that met protocol specifications. An additional 10 months, not included in the original projected project schedule, were required to develop and test the prototype exercise unit and software. During the performance period, the software was further refined and modified. During this performance period, the project purchased a multi-port serial connector, another television, and an infrared device to control the television. See Task 3 for more details.

Task 3: Develop, install, test software to capture exercise data

During the first year, an exercise bicycle, television controller, computer, TV monitor and video game console was purchased to create the prototype. During this period a database and user interface was also developed. While the prototype was fully functional, it required the exercise monitor to reconfigure the TV controller for each participant prior to beginning exercise. Although the configuration was not complex, an error at any of the several steps would not control the television in accordance with the protocol. As a result, manual configuration caused a concern about the reliability of the study data obtained. Therefore, two new alternatives were considered. The first solution tested a television with a serial port connection to the PC, which was the most economical. Unfortunately, the program codes provided by the television manufacturer were not reliably responsive when submitted from the personal

computer. Some features worked occasionally, other required actions did not work at all. The television manufacturer was unwilling to assist with troubleshooting so this alternative was considered unworkable.

The second alternative was an infrared unit interfaced with the PC and attached to the television, which replicated the signal sent by the television remote control device. This solution proved to be fully effective, and programming was performed to include remote infrared signals to automatically turn the television on and off at the start and ending of the exercise activity. Additional programming and configuration will be necessary to ensure there is no cross communication between exercise units while multiple users are actively exercising. However, no problems are anticipated as the infrared transmitter is taped directly to the infrared receiver on the television. Final testing will be performed after receipt of the start letter, and additional equipment is purchased.

Task 4: Hire & train research staff on equipment and protocol procedures

Hiring of the research coordinator and research assistants was deferred as a result of the protocol submission delays and the development of the exercise equipment prototype and related software. These positions will be filled after receipt of the start letter. It is anticipated that personnel training on the equipment and protocol procedures will be completed in 2 weeks.

Task 5: Pilot test procedure & equipment on 5 volunteers (no data collection)

Initial testing of connectivity and functionality was completed using the existing project team staff. Testing with the volunteers will be finalized following assembly, installation, and testing of all of the exercise equipment units at the study site.

Task 6: Recruit & identify participants

Participant recruitment will begin when protocol approval is received from the second-level review authority and the start letter is awarded.

Task 7: Assess, randomize, run study

Participant assessments, randomization, and exercise protocol implementation will begin upon receipt of second-level review authority approvals.

Task 8: Analyze data and complete final report

Because of the delays encountered during the protocol process, it is anticipated that the PI will request a no-cost extension in order to effectively complete the data analysis and final report.

RESEARCH ACCOMPLISHMENTS:

- Modification of software to capture and record real time physiologic and other exercise-related study variables.
- Refinement of software to enable exercise performance data transfer from the bicycle ergometer to a personal computer database while the participant is exercising.
- Refinement of software to create unique user codes and allow the heart rate levels of as many as 4 participants to be monitored simultaneously on a single screen.

REPORTABLE OUTCOMES:

Due to unanticipated delays in the IRB approval (see Body-Task 1), protocol implementation was deferred until second-level IRB approvals are obtained. A no-cost extension was requested and approved for a third year of the project.

CONCLUSION:

It is premature to discuss any conclusions at this time. It is expected that after the data has been collected and analyzed later in the next performance period, a summary of the results and their impact will be discussed.

REFERENCES:

Not applicable at this time.

APPENDICES:

Appendix A: Diagram of Integrated Exercise Bicycle-Video Game Prototype and Related Procedures

SUPPORTING DATA:

Not applicable at this time.

Appendix A: Diagram of Integrated Exercise Bicycle – Video Game Prototype and Related Procedures



- Participant assigned unique identifier and physical data (height, weight, age, gender, blood pressure) recorded and stored in computer database.
- Wireless heart monitor chest strap transfers heart rate data to bicycle ergometer
- Software determines target heart rate zone based on stored participant data
- Wireless game controller interfaces with video game
- Game play continues while in target heart rate zone
 - Warning displayed on television screen if heart rate is under or over target zone
 - Television shuts off ending video game play if heart rate does not return to target zone
- Heart rates of up to 8 participants concurrently displayed and monitored on the computer
- Four separate channels are regulated through infrared controller (study group)
- Headphones are provided to avoid disrupting other participants